SHAMISEN
Nuclear Emergency Situations - Improvement of Medical and Health Surveillance

IRSN
INSTITUT DE RADIOPROTECTION ET DE SÛRETÉ NUCLÉAIRE

Faire avancer la sûreté nucléaire

SHAMISEN
Nuclear Emergency Situations
Improvement of Medical and Health Surveillance

Bilan du projet européen SHAMISEN

OPERA
OPEN PROJECT FOR EUROPEAN RADIATION RESEARCH AREA

GT CIPR

Paris, 03 mai 2017

Projet SHAMISEN

Objectif : améliorer les conditions de vie et le suivi dosimétrique, sanitaire et épidémiologique après un accident nucléaire

Cadre : Projet soutenu dans le cadre du 2e appel d'offre Operra

Coordinateur : ISGlobal (Creal) – Elisabeth Cardis

Consortium : 19 partenaires

Durée : 18 mois

Budget : 1.5 M€ (EC 0.8 M€)

Contexte

Retour d'expérience des accidents nucléaires

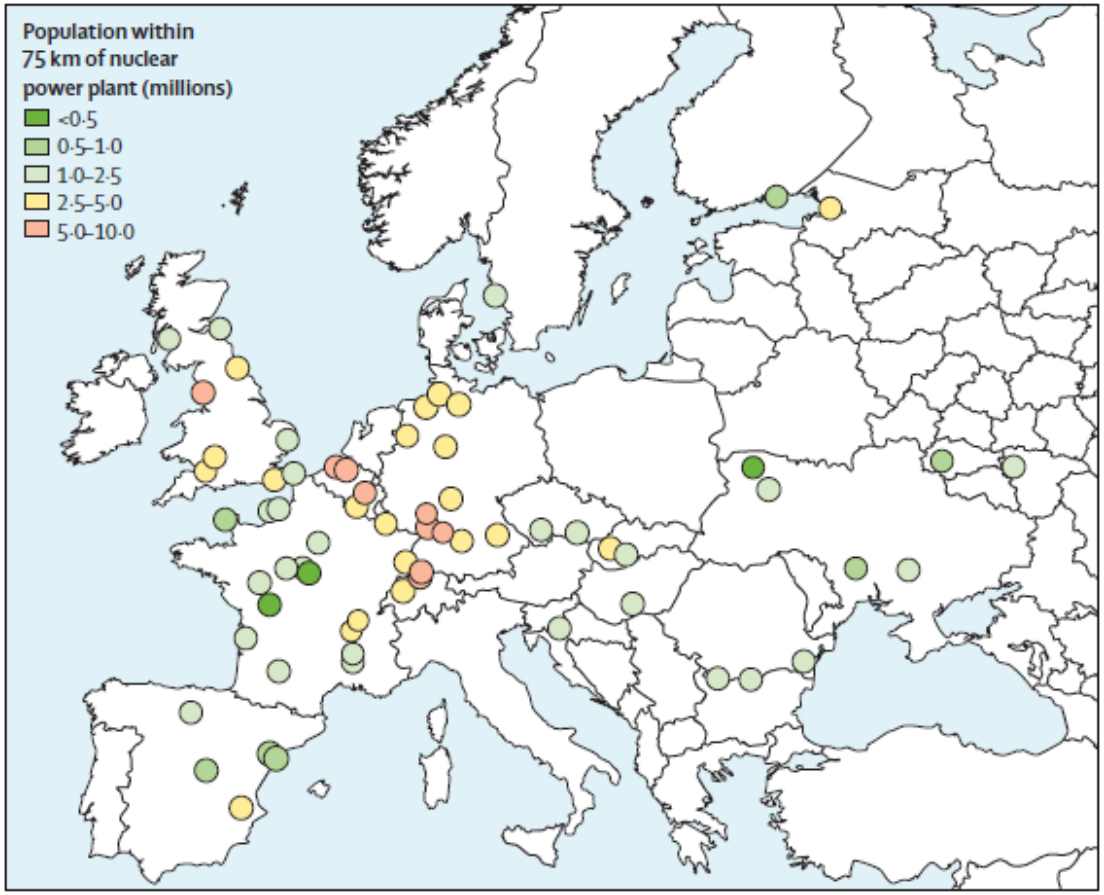
- Difficultés d'interprétation des résultats épidémiologiques sur les conséquences de l'accident de Tchernobyl

- Polémique sur le suivi sanitaire des habitants de la préfecture de Fukushima (dépistage des cancers de la thyroïde)

- Questions sur la santé des populations résidant en territoire contaminé, et sur les implications des évacuations et du retour après évacuation

Contexte

Possibilité d'un nouvel accident nucléaire



[Ohtsuru et al. Lancet 2015]

Objectifs du projet SHAMISEN

Nuclear Emergency Situations Improvement of Medical And Health Surveillance

Quelles recommandations pour améliorer la surveillance dosimétrique, sanitaire et épidémiologique en situation post-accidentelle ?

- **Tirer des leçons** de l'expérience des populations touchées par les accidents de Tchernobyl, de Fukushima et d'autres accidents radioactifs

- Afin d'élaborer des **recommandations** pour la surveillance médicale et sanitaire des populations affectées par des accidents radioactifs antérieurs et futurs

Objectifs spécifiques

Élaborer des recommandations

- sur l'utilisation de l'estimation des doses de radiation reçues en appui à la réponse d'urgence, aux décisions cliniques et au suivi à long terme des populations
- sur l'amélioration des évaluations du risque encouru par les populations et leur communication aux populations concernées
- sur la mise en place d'une surveillance sanitaire pertinente et, *in fine*, sur une amélioration des conditions de vie des populations affectées
- sur la prise en compte des attentes des populations impactées (en particulier celles vivant en territoires contaminés) et l'implication des parties prenantes

Approche multidisciplinaire

- Santé publique
- Sociologie
- Psychologie
- Médecine
- Epidémiologie
- Dosimétrie
- Métrologie
- Radioprotection
- Economie de la santé
- Communication

Consortium

19 organismes européens et japonais

- **Dosimétrie**
  - LDRI (SDE)
  - LEDI (SDI)
  - LDB (SRBE)
- **Épidémiologie**
  - LEPID (SRBE)
- **Ouverture à la société**
  - SCOSI

+ experts: Bromet E (US), Bushmanov A (Ru), Chumak V (Ua), Goto A (Jp), Grosche B (De), Hoffman (No), Igumnov S (By), Ivanov V (Ru), Rozhko A (By), Thomas G (UK), Tronko M (Ua)

Sous-tâches		Actions
ST1 Leçons tirées du suivi dosimétrique et sanitaire, de l'évacuation et de l'épidémiologie	1.1	Analyse critique des recommandations et des expériences sur l'évaluation des doses, l'évacuation, l'évaluation médicale des personnes potentiellement exposées et la reconstitution de la dose pour les études à moyen et long terme
	1.2	Analyse critique des programmes de surveillance médicale à long terme
	1.3	Analyse critique des leçons tirées de l'épidémiologie sur les risques d'exposition aux rayonnements dus aux accidents radiologiques
ST2 Leçons tirées des conditions de vie et de l'état de santé des populations	2.1	Expériences avec la population des Sámi concernant les retombées de Tchernobyl en Norvège
	2.2	Bilan des conséquences psychosociologiques de l'accident de Tchernobyl en Biélorussie, Russie et Ukraine
	2.3	Bilan des activités en cours mises en place après l'accident de Fukushima au Japon
ST3 Préparation et amélioration de la réponse post-accidentelle et du suivi sanitaire	3.1	Recommandations pour la collecte et la communication des données sur les doses aux différentes phases post-accidentelles et sur l'évaluation médicale en phase d'urgence
	3.2	Recommandations pour les décisions d'évacuation
	3.3	Conception de programmes de surveillance sanitaire qui répondent aux préoccupations de la population locale et améliorent leurs conditions de vie
	3.4	Recommandations pour améliorer le soutien professionnel des populations touchées
	3.5	Recommendations pour la préparation à l'épidémiologie post-accidentelle

ST4 - Actions transversales

- **CCA1** Engagement des parties prenantes
- **CCA2** Conséquences économiques des réponses à un accident radiologique
- **CCA3** Questions éthiques

ST5 - Gestion et coordination du projet

ST1 - Enseignements du suivi dosimétrique, de l'évacuation, de la surveillance médicale et de l'épidémiologie post-accidentels

Expérience des accidents de Tchernobyl, Fukushima, Three Mile Island et Fleurus

Enseignements

- Identification des pathologies d'intérêt, non limitées aux pathologies radio-induites
- Identification des populations pertinentes : intervenants, évacués, résidents, groupes spécifiques
- Importance de l'identification des individus et des mesures d'exposition durant la phase accidentelle
- Absence de préparation, manque de valeurs de référence
- Données manquantes, imprécision des estimations
- Impact bénéfique/négatif d'un dépistage ou d'une évacuation
- Nécessité de suivis sur le long terme
- Manque de formation, de communication

ST2 - Enseignements des conditions de vie et de l'état de santé des populations en territoires contaminés

Expérience des éleveurs de rennes scandinaves (Sámi), et des populations vivant dans des territoires contaminés après Tchernobyl (Core, Ethos) et Fukushima

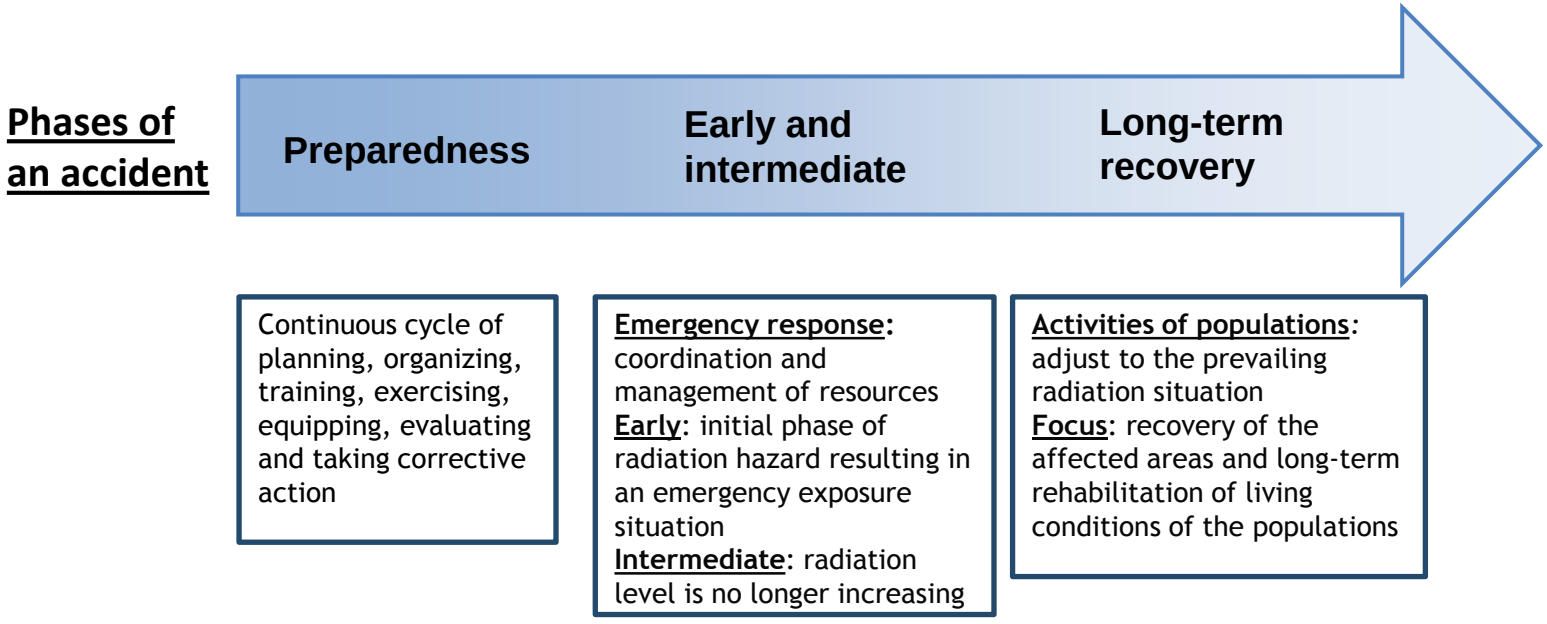
Enseignements

- Les préoccupations sur la santé dépassent les pathologies radio-induites (mode de vie, bien-être)
- Objectif des actions : contribuer à l'amélioration des conditions de vie
- Pondérer entre considérations scientifiques et attentes des populations
- Considérer les aspects éthiques d'un suivi sanitaire
- Importance du dialogue : écoute, communication, évaluation conjointe de la situation
- Rôle-clé des professionnels de santé, de l'éducation et des experts en radioprotection pour accompagner les actions locales
- Implication du public dans les processus de décision pour leur vie quotidienne
- Nécessité de formation des acteurs locaux

ST3 - Préparation et amélioration de la qualité de vie et du suivi des risques sanitaires post-accidentels

28 recommandations basées sur les enseignements de ST1 et ST2

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation



Principes généraux

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation

1. **The fundamental ethical principle of doing more good than harm should be central to accident management.**

2. **Recognize the difference between medical surveillance, health surveillance, health screening and epidemiology,** and their different objectives and data needs.

3. **Encourage a health surveillance strategy that targets the overall well-being of populations** and not only addresses radiation effects, but also psychosocial and socio-economical impacts induced by consequences of a nuclear accident.

4. **Ensure that health surveillance respects the autonomy and dignity of affected populations,** and is sensitive to any inequity in the distribution of risks and impacts.

5. **Review existing health monitoring systems with particular emphasis on cancer registries and, where needed, improve or establish new ones for epidemiological surveillance.** Disease registries must be expanded through better harmonization and linkage within and between countries. All aspects related to data protection and ethical rules need to be addressed and resolved.

6. **Adapt dosimetry and individual radiation monitoring** to the phase of the accident, the general situation and the different concerns and needs of people and society, and where needed, improve or establish new approaches.

7. **Build a radiation protection culture** among radiation protection experts, healthcare workers, professionals and the general.

R1 : faire plus de bien que de mal

R1. The fundamental ethical principle of doing more good than harm should be central to accident management.

Why*: Management of radiological accidents raises a number of ethical issues. A central question, and one that has been raised after both Chernobyl and Fukushima, is whether or not the response to the accident has caused more good than harm. Although the majority of radiation protection actions, including health surveillance, are directed towards reducing the impacts of exposure to ionizing radiation, most of these carry with them a multitude of direct and indirect consequences, including the inefficient use of health services, that can have a large impact on the welfare of affected and unaffected populations. Ethical considerations are also important for the design and implementation of health surveillance and epidemiological studies.*

How*:* SHAMISEN recognizes the need for a holistic approach to accident management and health surveillance if the aim of doing more good than harm is to be realized. This fundamental approach underlies, and is reflected in, many of the following recommendations. Although these focus primarily on health surveillance and epidemiology, they also cover the more general health implications of evacuation, and address challenges with communication and stakeholder engagement in accident management.

Who*:* All players involved in emergency preparedness, dose assessment, evacuation, health surveillance, and communication; this includes authorities, academic and other research institutes, NGOs, etc.

Phase de préparation

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation

8. **Establish early response and communication protocols** with responsibilities and roles clearly laid out, engage the different stakeholders in the establishment of these protocols, and prepare the necessary material and channels to communicate with the public (including social media).

9. **Plan sheltering, evacuation and KI distribution protocols,** including prioritization of vulnerable populations (e.g. children and pregnant women), and appropriate balancing of life-protection actions against the potential health impacts of evacuation, particularly for patients and nursing home residents.

10. **Prepare and facilitate training and information material for local professionals** by providing skills and knowledge adapted to healthcare and other professionals (practitioners, nurses, teachers) as well as other stakeholders (local authorities, NGOs, journalists and the general public).

11. **Prepare frameworks and checklists for epidemiological protocols,** questionnaires and consent forms for individual dosimetric and health monitoring and prepare appropriate databases through local, national and international coordination, ensuring ethics approvals.

12. **Prepare action frameworks focused on dose assessment** for workers and populations, with the objectives of 1) maximizing the number of individuals monitored and 2) collecting and maintaining the results and other relevant data (e.g. location at the time of the accident) for future dose reconstruction, health surveillance and, where appropriate, epidemiology.

13. **Foster participation of populations and communities** by engaging them in emergency preparedness, including planning for post-accident health surveillance and, where appropriate, epidemiology.

R11 : préparer le cadre d'un suivi épidémiologique

R11. Prepare frameworks and checklists for epidemiological protocols, questionnaires and consent forms for individual dosimetric and health monitoring and appropriate databases through local, national and international coordination, ensuring ethics approvals.

Why: Lessons learned from previous accidents indicate that implementation of post-accidental epidemiologic studies is very difficult, in particular because of the lack of pre-existing organizational framework, material or protocol hence the need to start preparations from scratch.

How: A framework and checklists could be prepared in advance, to be adapted to the specificities of an accident, which, in Europe, would likely affect several countries, including:

- Questionnaires and associated consent forms for the collection of individual dosimetric and health data and use of health care data, translated into different languages;
- Checklists for epidemiological protocols, with particular emphasis on specific diseases associated with radiation exposure and other indirect health consequences, taking into account economic, social difficulties faced by the affected population, and potential health impact of an evacuation;
- A priori criteria for the definition of study populations based on evacuation, definition of post-accidental exposure zones and clean-up worker status;
- Identification of the actors to be involved in post-accidental epidemiologic and public health studies, defining roles, actions and responsibilities of each institute or administration;
- Jointly developed procedures between radiation protection specialists (emergency measurements), public health/or disaster managers (rosters), epidemiologists and other researchers to allow collection and conservation of important data considering feasibility of biobanking for future epidemiological studies;
- Coordination of the creation of databases to ensure the ability to link within and between countries, and anticipate pitfalls in data access and sharing related to ethical and data protection aspects.

Who: Health authorities, academic and other research centres.

Phase précoce et intermédiaire

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation

14. **Provide rapid, transparent and coherent information (e.g. plant conditions, radiation dose, radiation protection actions)** by ensuring information flow between nuclear plant representatives, authorities and experts in order to guide evidence-based decisions, and ensure this information is communicated to the population through different channels, including social media.

15. **Optimise the timing and support for sheltering and evacuation** to reduce radiation exposure, avoid negative health effects arising from evacuation or relocation, and provide the necessary medical and psychological support.

16. **Create a common roster, collecting minimum prerequisite information from affected population** to allow efficient medical and health follow-up and facilitate future epidemiological studies, where feasible to be shared between relevant organizations with appropriate pre-obtained ethics approvals.

17. **Record and store all radiation-related dosimetry data** (both for workers and for the public) to ensure traceability of all measurements, even those that do not appear relevant from an immediate radiation protection viewpoint, since these may be crucial for accurate dose reconstruction at a later date.

18. **Provide support to populations and individuals who wish to make their own measurements**, recommending reliable equipment and resources (e.g. apps, social media, information centres) that can contribute to the characterization of population exposure and its evolution.

R16 : créer un registre commun

R16. Create a common roster collecting minimum prerequisite information from affected population to allow efficient medical and health follow-up and facilitate future epidemiological studies, where feasible to be shared between relevant organizations with appropriate pre-obtained ethics approvals.

Why: Main limitations of previous post-accidental health surveillance and epidemiologic studies were the difficulty of clearly defining and reaching the affected populations and the lack of minimal individual information. The creation of a roster of nuclear accident-affected persons during the emergency phase is a major element for the success of post-accidental health surveillance and epidemiology.

How: All persons affected by a nuclear accident should, if they give consent, immediately after the accident or later, be registered in a roster, with special attention for those evacuated and/or monitored. Registration would involve signing an informed consent form that allows the collection of identifying information, contact details (addresses, email, telephone number), linkage to population–based, as well as health and social care, registries and dose registries for follow-up and, if appropriate, dosimetric and/or medical surveillance and acceptance to complete a short questionnaire about sheltering, stable iodine supplementation and individual dose assessment, to allow reconstruction of doses due to early exposure. Ideally, all information would be gathered in a pre-formatted database that can be shared and completed by different team/organisms involved in the management of the various phases of the accident. The creation of such roster would be prepared in advance, in close collaboration with dosimetrists and public health practitioners, and adaptable to the specificities of the accident (see R11). This roster should be maintained in the post accidental phase as a basis for health and epidemiological surveillance.

Who: Radiation protection, civil protection and health authorities, interior ministry, representative of the state at local level.

R18 : aider la population à s'approprier les mesures

R18: Provide support to populations who wish to make their own measurements, recommending reliable equipment and resources (e.g., apps, social media, information centres) that can contribute to the characterisation of population exposure and its evolution.

Why: Self-made measurement (e.g. of activity in foodstuff, contamination of the environment, individual internal and external doses) can serve a number of purposes, beyond dose reconstruction and surveillance, creating opportunities for providing information to individuals and empowering them to take an active role in their own radiation protection decisions, thus regaining control on their lives. Experiences after the Chernobyl and Fukushima accidents have clearly shown that dosimetry and radiation measurement can help people to better apprehend and manage the situation, especially if they are trained and given the tools to make the measurements by themselves. It also facilitates understanding of individual doses and provides information on dose distribution in the population.

How: Although there may not be time for extensive training for measurements in the early phase, access to apps, mobiles and easy-to-use dosimetry devices could be provided rapidly. The development of such new technologies, with the support and advice of RP experts, should be encouraged: if not, populations will make use of existing unreliable apps and devices available widely on the internet. Data sharing among affected communities as well as on social media and the internet (crowdsourcing) is inevitable and may raise concerns about privacy, and scientific quality. Radiation protection institutes need to invest in this field and provide tools that could help a better understanding and interpretation of web-published measurement results. At the local level, the support of facilitators would be helpful. Populations outside the affected areas are also likely to require reassurance that their doses do not exceed the normal background levels.

Who: Radiation protection authorities, emergency preparedness authorities, technical experts and facilitators.

Phase de récupération à long terme

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation

19. **Continue dose assessment for workers and affected populations** as, in this phase, dosimetry and monitoring can be useful for increasing radiological protection knowledge and culture, reassurance, helping people manage their own exposure and supporting epidemiology.

20. **Continue dose measurement support to populations** by providing access to equipment such as personal dosimeters and mobile applications, food measurements and whole body counting, together with adequate expert counselling resources.

21. **Build networks of experts – local facilitators – population** in order to assist with the dissemination of reliable scientific information and facilitate two-way communication through the creation of dialogue spaces where affected people can voice their needs and worries and where they can receive practical advice on everyday life.

22. **Have plans for lifting of evacuation orders as soon as possible** to minimize the adverse effects of evacuation on physical and mental health of evacuees, and communities.

23. **Consider the preferences of people living in affected areas** when deciding whether mitigation actions should be revised, lifted or extended according to the evolution of the situation (e.g. evacuation orders, individual dose monitoring, psychosocial assistance, foodstuff surveillance).

R21 : construire un réseau

R21: Build networks of experts – local facilitators – population to assist with the dissemination of reliable scientific information and facilitate two-way communication through the creation of dialogue spaces where affected people can voice their needs and worries and receive practical advice on everyday life.

Why: In the different settings analysed, similar issues were found: mistrust of experts and authorities, lack of communication on health issues, and strong demand for counselling and advice on behaviour and practices that minimise risks. The case studies also highlighted the importance of listening to populations to identify their needs and improve their well-being, taking into account the specificities of the local situation. As previous assessments underline, the late-stage recovery phase is necessarily community focused and therefore driven by a broad range of stakeholders.

How: In order to assist with the healing process of the affected communities, sound, reliable scientific information should continue to be disseminated via institutional and local stakeholders to the radiation-affected communities via two-way communication and dialogue. The key role of local facilitators/interpreters (nurses, teachers, local doctors) should be recognized in this process as a liaison between the national and local levels and the capacity to listen, relay and balance the scientific expertise with local concerns and context. Examples are face-to-face risk communication (particularly by nurses and other healthcare workers) and the creation of dialogue spaces where affected families can voice their needs and worries, where they can receive advice on practical behaviour and identify means of improving their situation. Results of epidemiological studies when available should also be discussed with these stakeholders.

Who: Local authorities in coordination with radioprotection experts, community leaders, nurses, local doctors, teachers.

Phase de récupération à long terme

- Evacuation
- Surveillance sanitaire
- Epidémiologie
- Estimation des dose
- Communication et formation

24. **Adjust the compensation strategy to take into account economic and social upheavals** caused by the accident on infrastructures and community welfare.

25. **Do not recommend systematic thyroid cancer screening, but make it available** after providing complete information about potential benefit and detrimental effects on health and well-being.

26. **Decide on launching epidemiological studies,** clarifying objectives and expected results, justifying the design and methods and explaining the limitations.

27. **Ensure long-term sustainability of follow-up of populations at risk** for comprehensive ascertainment of potential health consequences of nuclear accident.

28. **Foster long-term participation of affected populations and communities** by engaging them in accident management decision-making processes, including dosimetric and health surveillance, with the aim of improving the efficiency of the interventions and maintaining radiation protection awareness.

R25 : ne pas lancer de dépistage systématique

R25. Do not recommend systematic thyroid cancer screening, but make it available after providing complete information about potential benefit and detrimental effects on health and well-being.

Why: It is important that countries have pre-existing high quality registry of diseases, particularly cancer. Without appropriate baseline rates, epidemiological surveillance cannot evaluate the possible impact of the accident on disease trends. Even when good quality disease registries are available, the apparent incidence of some occult or dormant diseases, may greatly increase, because of the sudden attention paid to the disease. This has been seen in Fukushima where high technology ultrasound screening has led to the detection of very large numbers of thyroid nodules, cysts, and potential cancer cases which may have never had any clinical manifestation (overdiagnosis). Given the good prognosis and slow evolution of the majority of thyroid cancers, screening will provide little benefit to the patient, but will cause considerable distress and anxiety, as well as negative consequences of unnecessary treatment.

How: It is not reasonable to consider a dose value below which screening is recommended or not. If a thyroid cancer screening should be carried out after a nuclear accident, one alternative might be a non-systematic screening based on free-will and informed decision, for those who wish to be monitored. A screening programme based on a clinical examination including thyroid palpation could be envisaged, with suspicious cases referred to ultrasound. Good communication about the potential harms and benefits of screening with the contaminated and non-contaminated populations is essential to allow them to make their own informed decisions.

Who: Health authorities, academic and other researchers, medical practitioners.

OPERA OPEN PROJECT FOR EUROPEAN RADIATION RESEARCH AREA

DRAFT

General

- The fundamental ethical principle of doing more good than harm should be central to accident management
- Recognise the difference between medical surveillance, health surveillance and epidemiology
- Promote a health surveillance strategy that targets the overall well-being of populations
- Ensure that health surveillance respects the autonomy and dignity of affected populations
- Review existing health monitoring systems and if needed improve or establish new ones for epidemiological surveillance
- Adapt dosimetry and individual exposure monitoring to the phase of the accident , the situation and the needs
- Build a radiation protection culture

	Preparedness	Early and Intermediate	Long-term
Evacuation	• Plan sheltering, evacuation and stable iodine distribution protocols	• Optimise timing and support for sheltering and evacuation	• Have plans for lifting of evacuation orders as soon as possible
Training and Communication	• Establish early response and communication protocols • Prepare and facilitate training and education material and resources • Foster participation of stakeholders and communities	• Provide rapid, transparent and coherent information on the situation	• Build networks of experts-local facilitators - population to facilitate communication • Consider the preferences of people living in affected areas when revising mitigation actions • Foster long-term participation of affected communities
Dosimetry	• Prepare action frameworks focused on dose assessment	• Collect and store all radiation-related dosimetry data • Provide support to populations who wish to make their own measurements	• Continue dose assessment for workers and affected populations • Continue dose measurement support to populations
Health surveillance		• Create a common roster, collecting minimum information from monitored and evacuated people	• Expand the health surveillance programme to take into account economic, social upheavals • Launch health screening based on appropriate justification and design
Epidemiology	• Prepare frameworks for epidemiological protocols	• Create a common roster, collecting minimum information from monitored and evacuated people	• Ensure long-term sustainability of follow up of populations at risk • Launch analytical epidemiological studies only where appropriate and informative

ST4 - Actions transverses

Questions éthiques

- Identifier les challenges éthiques liés à une surveillance sanitaire post-accidentelle
- Contribution à la formulation des recommandations générales

Conséquences économiques des réponses à un accident radiologique

- Revue des ressources et des couts sur la base d'accidents existants
- Estimation préliminaire des coûts relatifs au dépistage des nodules malins de la thyroïde dans la préfecture de Fukushima

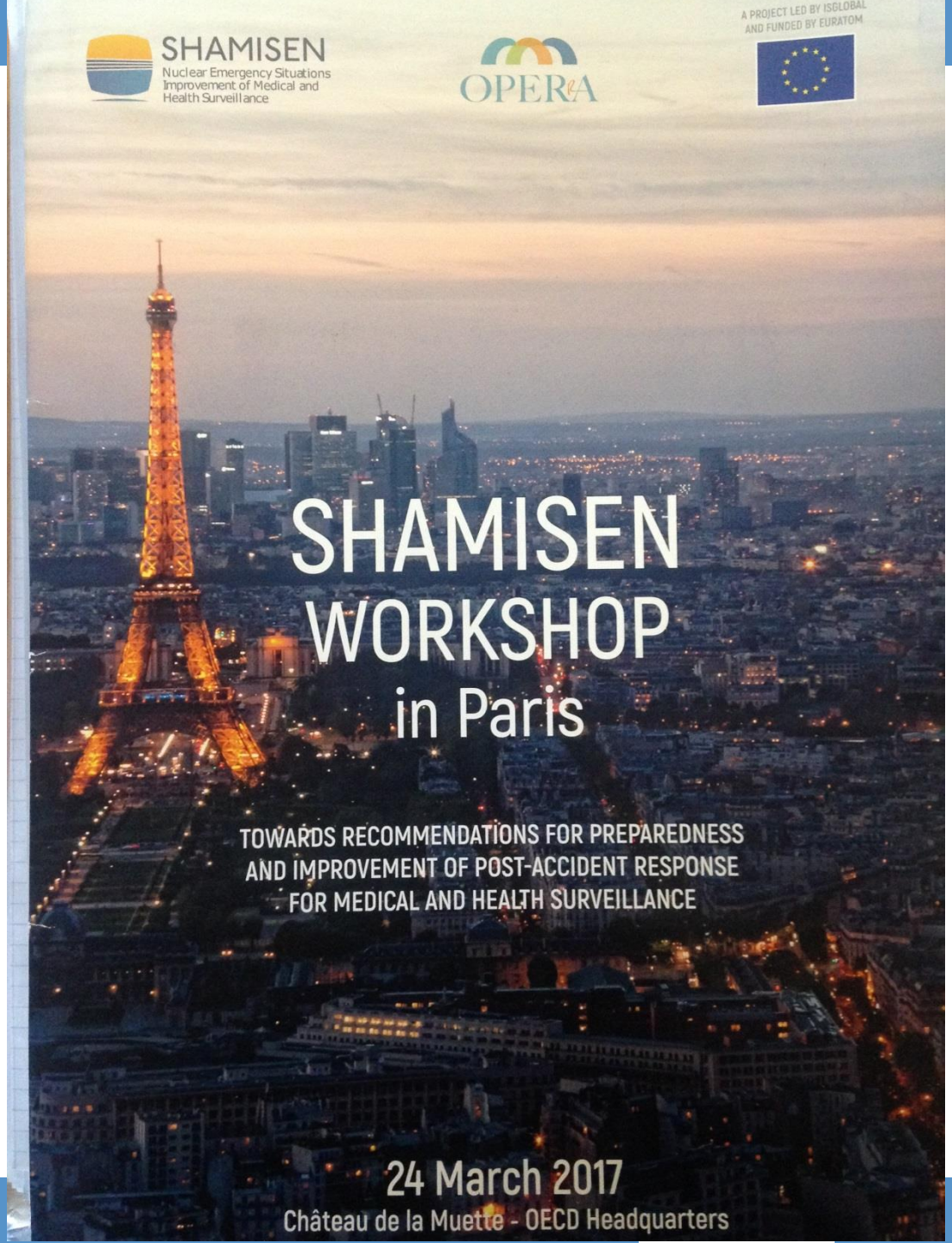
Engagement des parties prenantes

- Eléments favorisant l'implication des parties prenantes dans la surveillance dosimétrique et sanitaire post-accidentelle, et le développement d'une culture de radioprotection
- Circulation des recommandations préliminaires à une liste de parties prenantes
- Organisation d'un séminaire en Mars 2017

Workshop SHAMISEN

Paris
24 Mars 2017

Parties prenantes :
OMS, CIPR, AEN, MELODI, NERIS, EURADOS, CONCERT…



Calendrier du projet SHAMISEN

2016	Déc 2015	Kick-off meeting (Barcelone)
	…	Réunions en petit comité, au niveau des actions (Lyon, Munich, Norvège, Japon…)
2017	Déc 2016	Meeting « leçons tirées / enseignements » (Oslo) Rapports ST1 et ST2
	Mars 2017	Meeting final « recommandations » (Paris)
	Mai 2017	Rapport final

Consortium SHAMISEN

(OCDE, Paris, Mars 2017)

Merci
de votre attention

Grand merci à Enora Cléro
pour son aide dans la préparation de cette présentation

Plus d'information sur :

http://www.crealradiation.com/index.php/es/shamisen-home